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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,776	12/22/2000	Hans-Ulrich Demuth	20784/4	7886

21710 7590 09/19/2002

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BOSTON, MA 02111

EXAMINER

CHISM, BILLY D

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 09/19/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/745,776

Applicant(s)

DEMUTH ET AL.

Examiner

Billy D Chism

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-13 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7 and 13, drawn to an amino acid composition, classified in class 514, subclass 19.

Claims 1-7 are generic to a plurality of disclosed patentably distinct compounds comprising a combination of three prodrug compounds wherein: (i) the first compound, A, can be any one of 20 amino acids; (ii) the second compound, B, can be a bond between A and C or any one of 20 amino acids or proline, hydroxyproline, thiazolidinecarboxylic acid, dehydroproline, pipecolic acid, azetidinecarboxylic acid or aziridinecarboxylic acid; and, (iii) the third compound, C, is a stable inhibitor of DP IV that can be any one of aminoacylpyrolidide, aminoacylthiazolidide or N-dipeptidyl, O-acyl hydroxylamine. Applicant is required under 35 U.S.C. 121 to elect a single disclosed prodrug compound comprising one each of A, B and C above, wherein each of A, B and C are specified (i.e. A is L-Asp, B is proline, and C is aminoacylpyrolidide), even though this requirement is traversed.

Should applicant traverse on the ground that the prodrug compounds are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the prodrug compounds to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner

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finds one of the prodrug compounds unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other prodrug compounds.

- II. Claims 8-12, drawn to method of *in vivo* use of an amino acid composition, classified in class 514, subclass 14.

Claims 8-12 are generic to a plurality of disclosed patentably distinct compounds comprising a combination of three prodrug compounds wherein: (i) the first compound, A, can be any one of 20 amino acids; (ii) the second compound, B, can be a bond between A and C or any one of 20 amino acids, (iii) the third compound, C, is a stable inhibitor of DP IV without the C-terminal phosphonate residue. Applicant is required under 35 U.S.C. 121 to elect a single disclosed prodrug compound comprising one each of A, B and C above, wherein each of A, B and C are specified (i.e. A is L-Asp, B is proline, and C is aminoacylpyrolidide), even though this requirement is traversed.

Should applicant traverse on the ground that the prodrug compounds are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the prodrug compounds to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the prodrug compounds unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other prodrug compounds.

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2. Groups I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group I can be used in immunoassays, antibody production, molecular weight markers or as a class of controls.

3. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper. Although the search for the product of Group I might yield references to the methods of Group II, the searches are not coextensive, thus, additional searches would be required and would be burdensome to the examiner.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

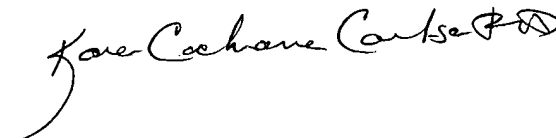
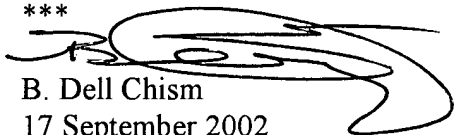
Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 703-306-5815. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

B. Dell Chism
17 September 2002



KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER